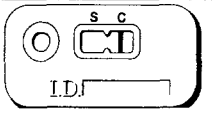
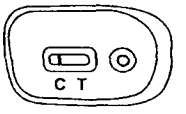
K022683

510(k) Summary

DEC 16 2002

The following table details the comparison of the SAS™ Blood/Serum/Urine hCG to the Modified SAS Serum/Urine hCG Test.

	SAS Serum/Urine hCG Test	**SAS Blood/Serum/Urine hCG**
Name	SAS Serum Urine hCG	SAS Blood/Serum/Urine hCG
Format	Lateral flow	Lateral Flow
Cassette		
Cassette Packaging	Individual Pouch	Individual Pouch
Sample Type	Serum or Urine	Serum, Urine or Whole Blood
Buffer	No	For whole blood sample only
Blood Cell Separation Media	No	Yes
Sensitivity	10 mIU/mL Serum 20 mIU/mL Urine	10 mIU/mL Serum 10 mIU/mL Whole Blood 20 mIU/mL Urine
Sample Size	3-4 drops	3 drops
Read Time	4 minutes Urine 7 minutes Serum	4 minutes Urine 7 minutes Serum 15 minutes Whole Blood
Kit Size	30, 50 Tests	1,25, 30, 50, 100 Tests

The SAS Blood/Serum/Urine Test utilizes the same antibodies and 90% of the same test construction of the Modified SAS Serum/Urine test. The most significant difference in the SAS Blood/Serum/Test is that it utilizes a red blood cell separation media that separates plasma from the whole blood cell component. These modifications do not affect the performance, safety or efficacy of the product. Please refer to the data included in this submission.

Prepared by: Ricardo R. Martinez on 08/06/2002.

SA Scientific, Inc
4919 Golden Quail
San Antonio, Texas 78240
210.699.8800
Fax: 210.699.6545

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Ricardo R. Martinez
Director of Regulatory Affairs
SA Scientific, Inc.
4919 Golden Quail
San Antonio, TX 78240

DEC 16 2002

Re: k022683
Trade/Device Name: SAS™ Blood/Serum/Urine hCG
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: October 28, 2002
Received: November 4, 2002

Dear Mr. Martinez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: SA Scientific, Inc.
4919 Golden Quail
San Antonio, TX. 78240
Ph: (210) 699-8800 Fax: (210) 6996545

Establishment Reg. No.: 1645225

501(k) Number: K022683

Device Name: SAS™ Blood/Serum/Urine hCG

Indications for Use: SAS™ Blood/Serum/Urine hCG is a visual and rapid test for the qualitative determination of human chorionic gonadotropin (hCG) in whole blood, serum or urine to aid in the early detection of pregnancy.

The test is for professional use.

Dian Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022683

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Prescription Use ✓ or Over-the-Counter _____